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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,669	10/31/2001	Jerome T. Hartlaub	11738.00046	5026

27581 7590 07/05/2006

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EXAMINER	
NAJARIAN, LENA	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,669	HARTLAUB, JEROME T.	
	Examiner	Art Unit	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 27-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20020326*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 12-26 (Group II) in the reply filed on 4/14/06 is acknowledged.

2. Claims 1-11 and 27-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/14/06.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: items 22 and 24 (Fig. 2), items 207 and 40 (Fig. 4), item 745 (Fig. 9), and item 30 (Fig. 5). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: item 820 (p. 15, para. [50], line 11). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The

disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because of using phrases which can be implied, such as "disclosed is a method and apparatus...." Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 19-20 and 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 19-20 and 25-26 recite the limitations for which there is no antecedent basis in the claims. In particular, the following passages lack or have vague antecedent basis:

(i) "the computing device": claim 19, line 1 and claim 25, line 1

(ii) Claims 20 and 26 incorporate the deficiencies of claims 19 and 25, through dependency, and are also rejected.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 12-15 and 17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Garcia (6,088,429).

(A) Referring to claim 12, Lebel discloses an implantable drug delivery device for delivering at least one drug to a patient comprising in combination (abstract of Lebel):

(a) at least one reservoir each containing at least one drug (para. 60 of Lebel);

(b) a drug scheduling module for determining whether the drug should be replenished (para. 179 of Lebel); and

(d) a telemetry module providing bi-directional communications with an external device (Fig. 3 of Lebel).

Lebel does not disclose an appointment scheduling module for scheduling an appointment to replenish the drug in the device and allowing the scheduling module to schedule the appointment.

Garcia discloses an appointment scheduling module for scheduling an appointment to replenish the drug and allowing the scheduling module to schedule the appointment (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Garcia within Lebel. The motivation for doing so would have been to provide an easier and higher accuracy system for refilling drugs (col. 6, lines 58–65 of Garcia).

(B) Referring to claim 13, Lebel discloses wherein the module contacts via the external device at least one entity, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient (para. 134 of Lebel).

Lebel does not expressly disclose an appointment scheduling module.

Garcia discloses an appointment scheduling module (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been to provide an easier and higher accuracy system for refilling drugs (col. 6, lines 58–65 of Garcia).

(C) Referring to claim 14, Lebel discloses the drug scheduling module receives data about the implantable drug delivery device, wherein the data is drug management instructions (para. 320 of Lebel).

Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(D) Referring to claim 15, Lebel discloses wherein the drug management instructions is deliver drug to a specified location (para. 204 of Lebel).

Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(E) Referring to claim 17, Lebel discloses wherein the drug scheduling module includes a drug management algorithm to forecast when a next refill of pump reservoir is required (para. 179, para. 207, and para. 318 of Lebel).

(F) Referring to claim 18, Lebel does not disclose wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

Garcia discloses wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is the patient (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been to provide an easier and higher accuracy system for refilling drugs (col. 6, lines 58–65 of Garcia).

Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(G) Referring to claims 19 and 20, Lebel discloses wherein the computing device is operatively coupled to the entity (see Fig. 3 of Lebel).

Lebel does not disclose wherein the computing network is the Internet.

Garcia discloses wherein the computing network is an Internet (col. 9, lines 58-59 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been to provide easier access that is available world wide (col. 9, lines 58-59 of Garcia).

(H) Referring to claim 21, Lebel discloses an implantable drug delivery device, comprising (para. 204 and Fig. 3 of Lebel):

(a) a housing (para. 204 and Fig. 3 of Lebel);

(b) a drug reservoir carried in the housing configured to contain a therapeutic substance (para. 204 and Fig. 3 of Lebel);

(c) a flow control coupled to the drug reservoir for controlling the flow of the therapeutic substance from the drug reservoir through an infusion port (para. 204 and Fig. 3 of Lebel);

(d) electronics coupled to the flow control and a power source (para. 204 and Fig. 3 of Lebel);

(e) a telemetry module coupled to the electronics (para. 204 and Fig. 3 of Lebel);

(f) memory coupled to the electronics, the memory containing pump refill criteria and other refill criteria (para. 204, para. 179, para. 186, and Fig. 3 of Lebel);

(g) a monitoring module coupled to the memory and the electronics that monitors at least one pump operation variable (para. 204, para. 179, and para. 186 of Lebel); and,

(h) a refill module coupled to the memory and the electronic, the refill module configured to calculate at least one relationship among the pump refill criteria, other refill criteria, and monitored pump variables, the refill module configured to decide whether a pump refill activity should be reported, and the refill module configured to activate the telemetry module to report a refill activity (para. 204, para. 179, para. 186, and Fig. 3 of Lebel).

Lebel does not expressly disclose patient scheduling.

Garcia discloses patient scheduling (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The motivation for doing so would have been to provide an easier and higher accuracy system for refilling drugs (col. 6, lines 58–65 of Garcia).

(I) Referring to claim 22, Lebel discloses wherein the refill module determines whether an appointment is necessary to perform a pump refill (para. 179 and para. 186 of Lebel).

Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(J) Referring to claim 23, Lebel discloses wherein the refill module communicates via the telemetry module with an external device (Fig. 3 of Lebel).

(K) Referring to claim 24, Lebel does not disclose wherein the scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

Garcia discloses wherein the scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is the patient (col. 6, lines 17-28 of Garcia).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Garcia within Lebel. The

motivation for doing so would have been to provide an easier and higher accuracy system for refilling drugs (col. 6, lines 58–65 of Garcia).

Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(L) Claims 25 and 26 repeat the same limitations of claims 19 and 20, and are therefore rejected for the same reasons given for those claims.

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Garcia (6,088,429), and further in view of Akers et al. (6,112,182).

(A) Referring to claim 16, Lebel and Garcia do not disclose wherein the drug scheduling module receives drug management data selected from the group consisting of name of drug manufacturer, date drug was manufactured, and name of pharmacy carryng the drug.

Akers discloses wherein the drug scheduling module receives drug management data such as name of drug manufacturer (col. 5, lines 18-21 of Akers).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Akers within Lebel and Garcia. The motivation for doing so would have been for a comprehensive drug record (col. 5, lines 18-21 of Akers).

Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a medical reminder system and messaging watch (6,075,755); a method and apparatus for supplying a medical treatment composition to a patient (5,730,722); an implantable telemetric transcranial Doppler device (US 6,468,219 B1); an RF coupled, implantable medical device with rechargeable back-up power source (5,733,313); and an implantable electrical transducer powered from capacitive storage energy source (6,099,495).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

In
6-13-06

C. LUKE GILLIGAN
PATENT EXAMINER